

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Shiatsu massage on restlessness and vital signs of patients undergoing mechanical ventilation

Protocol summary

Study aim

The effect of Shiatsu massage on agitated and vital signs of patients undergoing mechanical ventilation

Design

Clinical trial with control group, with parallel groups, Single blinded, randomized

Settings and conduct

In this study will be selected 68 patients hospitalized in the intensive care unit of valiasr hospital in arak city and with random blocks will be divided to two groups of experimental and control. Alternate shiatsu will be performed for 5 minutes massage and 2-minute rest to 20 minutes by the intervention group, control group during this period will receive touch without pressure for 20 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 30 to 60 years Level of consciousness higher than 7 on the Glasgow standard Restlessness behavior according to Richmond criteria in the range of 2+ to 4 + exclusion criteria: Any life-threatening emergency situation skin diseases such as ulcers and infections of hand

Intervention groups

Intervention group: Alternate shiatsu will be performed for 5 minutes massage and 2-minute rest to 20 minutes. Control group: Touch without pressure will be done for 20 minutes.

Main outcome variables

Agitation, Vital signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N9**

Registration date: **2020-01-17, 1398/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-17, 1398/10/27**

Update count: **0**

Registration date

2020-01-17, 1398/10/27

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-11, 1398/07/19

Expected recruitment end date

2020-04-07, 1399/01/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Shiatsu massage on restlessness and vital signs of patients undergoing mechanical ventilation

Public title

The effect of Shiatsu massage on agitated and vital signs of patients undergoing mechanical ventilation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 30 to 60 years Level of consciousness higher than 7 on the Glasgow standard Restlessness behavior according to Richmond criteria in the range of 2 + to 4 +

Exclusion criteria:
Paralyzed hands Spinal cord injury

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to allocate the patients randomly into two groups of treatment and control, at first 22 blocks of 4 with C and T letters (The letters indicate the intervention and control groups) are created in each 2 patients are belonged to the intervention group and 2 patients are belonged to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 68 letters. Each letter will be placed in a sealed packet according to the obtained sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
It should be noted that the nurse who will measure the vital signs and the patient's restlessness level through the Richmond Instrument will be unaware of the type of intervention being performed, so it will be a single blind study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City

Arak

Province

Markazi

Postal code

38481-76941

Approval date

2019-09-29, 1398/07/07

Ethics committee reference number

IR.ARAKMU.REC.1398.196

Health conditions studied

1

Description of health condition studied

Agitation

ICD-10 code

R46

ICD-10 code description

Symptoms and signs involving appearance and behavior

Primary outcomes

1

Description

Agitation

Timepoint

Before and after the intervention

Method of measurement

Richmond agitation scale

2

Description

Systolic blood pressure

Timepoint

Before and after the intervention

Method of measurement

Digital pressure indicator gauge

3

Description

Dyastolic blood pressure

Timepoint

Before and after the intervention

Method of measurement

Digital pressure indicator gauge

4

Description

Pulse rate

Timepoint

Before and after the intervention

Method of measurement

Radial Pulse

5

Description

Respiratory rate

Timepoint

Before and after the intervention
Method of measurement
Observation chest in a minute

6

Description
Temperatures
Timepoint
Before and after the intervention
Method of measurement
Thermometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group at one time alternate shiatsu on the Hugo points will be performed for 5 minutes massage and 2-minute rest to 20 minutes. Vital signs and severity of agitation before and after the intervention, using the Richmond score will be determined.
Category
N/A

2

Description
Control group: Patients in the control group do not receive any Shiatsu massage intervention on the part of the researcher. In this group, only touch without pressure will be done for 20 minutes.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital Arak
Full name of responsible person
Masoumeh Garshasbi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Masoumeh Garshasbi
Position
MSc student of nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Position

Academic Instructor Faculty Of Nursing

Latest degree

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Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available